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EXAMINER

JANG, CHRISTIAN YONGKYUN

ART UNIT	PAPER NUMBER
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3735

NOTIFICATION DATE	DELIVERY MODE
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12/28/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/506,872	Applicant(s) GIRON ET AL.	
	Examiner CHRISTIAN Y. JANG	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-100, 102-104 and 110-122 is/are pending in the application.
- 4a) Of the above claim(s) 110-119 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-100, 102-104 and 120-122 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Amendment filed on August 4th, 2009. Claims 66-104 and 110-122 are pending in the instant application. Amendments to claims 66, 67, 78-82, 89, 95, and 96 are acknowledged by the examiner. Claims 120-122 have been newly added. Claims 110-119 remain withdrawn.

Claim Rejections - 35 USC § 112

2. Claim 122 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

3. As to claim 122, the claim recites a pump. The specification, however, states that the need for a pump is obviated when a breathing tube is used for collecting the sample. Since claim 66, which claim 122 is dependent upon, teaches the use of a breath conduit to convey the exhaled breath from the subject, the specification teaches away from this specific combination.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Art Unit: 3735

5. Claims 66-74, 76-89, 91, 95, 96, 98-100, 102, 104, and 120-122 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,797,885) in view of Baghdassarian (US 2003/0050567).

6. As to claim 66, Lemelson teaches a system for collecting a plurality of samples of breath of a subject (Abs) comprising: a breath conduit adapted to convey breath from the subject (11); a sensor for determining a characteristic of said breath exhaled from the subject (28), a plurality of sample containers for collection of said plurality of samples (20); a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (column 5, lines 30-35). Lemelson fails to teach a sample distributor which directs the samples according to the sensed characteristics of said exhaled breath. However, Baghdassarian, in a breath collection system, teaches that the activation of the collection process can be made to activate according a signal from a carbon dioxide sensor ([0048]). As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Baghdassarian so that sample collection can be made only when necessary.

7. As to claim 67, Lemelson teaches a controller, where said different samples of said exhaled breath are directed to different ones of said plurality of sample containers according to said controller (column 5, 32-35).

8. As to claims 68 and 100, Lemelson discloses the invention substantially as claimed. Lemelson does not teach a sample distributor which is operated manually. However, Lemelson does disclose an automatic sample distributor and it would not be

Art Unit: 3735

beyond the ability of one of ordinary skill in the art to utilize a manually operated sample distributor when the end result is equivalent.

9. As to claim 69, Lemelson teaches a system according to claim 66 wherein said sample distributor directs said samples at predetermined times (column 7, lines 47-52).

10. As to claims 70 and 85, Lemelson discloses the invention substantially as claimed. Lemelson does not teach that the predetermined times are at fixed time intervals. However, it is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to recognize that gas samples collected at fixed time intervals would allow comparative analysis without a time-dependent variable. Thus, it would be obvious to one of ordinary skill in the art to modify Lemelson with a fixed time interval mechanism in order to increase the accuracy of the device.

11. As to claim 71, Lemelson teaches the predetermined times are determined by a characteristic of said breath of the subject (column 7, lines 17-21).

12. As to claim 72, Lemelson teaches the characteristic of said breath is at least one of the carbon dioxide concentration, the oxygen concentration, the excess pressure, the temperature, the humidity, the flow rate and the sound of said breaths (column 6, line 65 to column 7, line 4).

13. As to claim 73, Lemelson teaches the predetermined times are determined by at least one physiological characteristic of the subject (column 6, lines 14-17).

14. As to claim 74, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (column 6, lines 14-17).

Art Unit: 3735

15. As to claim 76, Lemelson teaches the breath conduit comprises a breath tube through which the subject provides breath by blowing (11).

16. As to claim 77, Lemelson teaches a one-way check valve for directing said breath samples from said breath tube towards said plurality of sample containers (column 2, lines 27-31).

17. As to claim 78, Lemelson, once combined with Baghdassarian, teaches a valving system to select at least part of said breath for transfer to said sample distributor, according to said carbon dioxide levels (column 5, lines 39-42).

18. As to claim 79, Lemelson, once combined with Baghdassarian, teaches a valving system to select at least part of said breath for transfer to said sample distributor, according to said characteristic of said breath (column 5, lines 39-42).

19. As to claims 80-83, Baghdassarian teaches the sensor is a capnographic analyzer and carbon dioxide levels comprises carbon dioxide concentrations, waveforms, or both ([0048]) and the collection is determined when the concentration is at a plateau value such that alveolar air is sampled ([0047]; Fig. 4).

20. As to claim 84, Lemelson teaches the controller causes said sample distributor to direct said samples at predetermined times (column 7, lines 47-52).

21. As to claim 86, Lemelson teaches the predetermined times are determined by a characteristic of said breaths of the subject (column 7, lines 17-21).

22. As to claim 87, Baghdassarian teaches the characteristic of said breath is at least one of CO₂ concentration, O₂ concentration, excess pressure, temperature, humidity, flow rate, and sound of said breaths ([0048]).

Art Unit: 3735

23. As to claim 88, Lemelson teaches the predetermined times are determined by a physiological characteristic of the subject (column 7, lines 16-21).

24. As to claim 89, Lemelson teaches the at least one physiological characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, blood pressure, pulse rate, gastric pH value and temperature (column 6, lines 14-17).

25. As to claim 91, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (column 2, lines 39-46). Although Lemelson does not specify a container with rigid walls, the use of a technique to controllably flush and clean residual gas is indicative of a container that has not started out deflated, and thus has the rigidity to sustain an internal volume or space.

26. As to claim 95, Lemelson teaches a system for collecting a plurality of samples of breath of a subject comprising: a breath conduit adapted to convey breath from the subject (11); a valving system (col 5, lines 39-42); a plurality of sample containers for collection of said plurality of samples (20); and a sample distributor which directs different predetermined samples of said breath to different ones of said plurality of sample containers (col 5, 30-35). Lemelson teaches a controller causing said sample distributor to direct said different predetermined samples to said different ones of said plurality of sample containers (74). Lemelson fails to teach a valving system which directs the samples according to the sensed characteristics of said exhaled breath. However, Baghdassarian, in a breath collection system, teaches that the activation of the collection process can be made to activate only when carbon dioxide levels are

Art Unit: 3735

within acceptable ranges ([0048]). Although Baghdassarian fails to specifically mention a capnographic analyzer, it teaches the monitoring of carbon dioxide levels in real time, which is the definition of a capnograph. As such, it would have been obvious to one of ordinary skill in the art to modify the breath collection device taught by Lemelson with a collection activation setup taught by Baghdassarian so that sample collection can be made only when necessary.

27. As to claim 96, Lemelson teaches the at least one characteristic of the subject is selected from a group consisting of the subject's breath composition, breath rate, heart rate, blood pressure, gastric pH value and temperature (col 6, lines 14-17).

28. As to claim 98, Lemelson teaches said breath conduit comprises a breath tube (11).

29. As to claim 99, Lemelson teaches a pressure sensor for determining the pressure of said breath (Abs), and wherein said valving system is actuated according to said pressure of said breath (col 2, lines 32-39).

30. As to claim 102, Lemelson teaches the controller prompts the subject at predetermined times to provide breath by blowing (col 8, lines 46).

31. As to claim 104, Lemelson teaches at least one of said sample containers has rigid walls and is evacuated before collection of said samples (col 2, lines 39-46).

32. As to claim 120, Lemelson teaches that the samples are adapted to be analyzed in one or more breath tests (col. 2 lines 33-52).

33. As to claim 121, Lemelson teaches one or more breath tests comprising the determination of bacterial overgrowth (col. 26-36).

Art Unit: 3735

34. As to claim 122, Baghdassarian teaches the use of a pump adapted to facilitate the collection of the breath sample by means of its suction effect and its continued motion through the sample distributor (55).

35. Claims 75 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Baghdassarian (US 2003/0050567) as applied to claims 66 and 95 above, and further in view of Dietz (USP #5,005,571).

36. As to claim 75 and 97, Lemelson and Baghdassarian discloses the invention substantially as claimed. However, Lemelson and Baghdassarian does not disclose a breath conduit in the form of an oral/nasal cannula.

Dietz teaches a oral/nasal cannula (Abs) for the purpose of use in a breathing monitoring apparatus (Abs).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Baghdassarian to employ a cannula as taught by Dietz in order to allow for the use of the device where the user no longer has to actively engage the device.

37. Claims 90 and 103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Baghdassarian (US 2003/0050567), as applied to claims 66 and 95 above, and further in view of Opekun, Jr. et al. (USP #5,140,993).

Art Unit: 3735

38. As to claims 90 and 103, Lemelson and Baghdassarian discloses the invention substantially as claimed. However, Lemelson and Baghdassarian do not disclose a sample container in the form of a flexible bag.

Opekun teaches a flexible, inflatable plastic bag (Abs) for the purpose of collecting a breath sample.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify a breath collection device taught by Lemelson having a collection activation setup taught by Baghdassarian with an inflatable plastic bag as taught by Opekun which would allow the means for collection to be kept to a minimal volume prior to deployment.

39. Claims 92-94 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lemelson (USP #5,787,885) and Baghdassarian (US 2003/0050567), as applied to claim 80 above, and further in view of Daniels et al. (USP #6,099,481).

40. As to claim 92, Lemelson and Baghdassarian discloses the invention substantially as claimed. However, Lemelson and Baghdassarian do not disclose a valving system adapted to direct breath exhaled when said CO₂ concentration is at the plateau into one of said containers and breath inhaled when said CO₂ concentration is at the baseline into a second one of said sample containers.

Daniels teaches respiratory measurements which includes carbon dioxide elimination, airway dead space, and physiologic dead space which clearly shows the

Art Unit: 3735

plateau during exhalation and the baseline for inhalation for the purpose of deciphering the volume of CO₂ elimination and alveolar volume (col 8 line 61 to col 9 line 10).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the breath collection device taught by Lemelson, a collection activation setup taught by Baghdassarian, and the capnography sensor taught by Hoberman to capture breath samples during these baseline and plateau periods in order to enable to machine to decipher such physiological parameters as CO₂ elimination and alveolar volume as taught by Daniels.

41. As to claim 93, Lemelson, Baghdassarian, and Daniels disclose the invention substantially as claimed. Lemelson teaches sample containers which absorb a predetermined gas of said breath of the subject (col 6, lines 37-43). Lemelson, Baghdassarian, and Daniels fail to teach a heater for expelling said predetermined gas of said breath of the subject. However, Lemelson recognizes the importance of cleaning out the chambers, utilizing a water trap and flushing mechanism to clean out the chambers (Fig. 2, 29). In addition, the expulsion of gas from a container by means of using the properties of thermal expansion is a well known technique in the field. It is the examiner's position that it would not be beyond the ability of one of ordinary skill in the art to modify the breath collection device taught by Lemelson, a collection activation setup taught by Baghdassarian, and the capnography sensor taught by Hoberman with a heated chamber in order to remove residual sample gas molecules which may adversely affect future usage of the container as an alternative to the existing liquid/water trap.

Art Unit: 3735

42. As to claim 94, Lemelson, Baghdassarian, and Daniels disclose the invention substantially as claimed. Lemelson teaches that said predetermined gas is a volatile organic compound. Although Lemelson does not explicitly state the phrase "volatile organic compound", the examiner notes that there is no limiting definition within the applicant's disclosure as to the limitations of the phrase. Thus, the examiner is taking the broadest reasonable definition of the phrase, in light of the disclosure, wherein "volatile organic compound" may mean any substance detectable from human expired breath that has high enough vapor pressure to vaporize into a gaseous form. Since Lemelson discloses that his teachings can be used to automatically analyze the chemical contents within the breath of living beings for analysis of a variety of conditions and diseases of said living being, the examiner regards Lemelson to teach the limitations of the claim.

Response to Arguments

43. Applicant's arguments with respect to claims 66-100, 102-104 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

44. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

Art Unit: 3735

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTIAN Y. JANG whose telephone number is (571)270-3820. The examiner can normally be reached on Mon. - Fri. (8AM-5PM) EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3735

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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12/07/09